K120137

FEB 14 2012

510(k) Summary – Victory Guidewires
Special 510(k)

Device Name	Victory Guidewire
Submitters name	Brivant Ltd, Parkmore West Business Park, Galway, Ireland
Application Correspondent	Kenneth Walsh Senior QA/RA Engineer Brivant Ltd, t/a Lake Region Medical International R&D Centre Tel: +353 91 385037 Fax: +353 91 766598
Summary Preparation Date	20th December 2011
Device Name & Classification	Trade Name: Victory Guidewire Common Name: Guidewire Classification Name: Catheter, Guidewire Device Classification: Class II, 21 CFR §870.1330 Product Code: DQX
Intended Use	Indications for Use: The guidewires are intended to facilitate the placement and exchange of balloon catheters or other interventional devices within the peripheral vasculature during Percutaneous Transluminal Angioplasty (PTA) or other intravascular interventional procedures. Contraindications: The Guidewires are not intended for use in the coronary or cerebral vasculatures or in patients judged not acceptable for percutaneous intervention.
Device Description	The Victory Guidewire range are a disposable medical device designed for single use only. The device is intended to facilitate the placement of percutaneous devices during Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature. The family consists of a PTFE coated 195cm or 300cm, 0.014" or 0.018" diameter stainless steel core wire, one end of which is reduced in diameter in a progressive fashion through a centreless grinding operation. The profile of this reduced section affords the product a reduced area of stiffness and can be varied to produce 6 various levels of support.

Predicate Devices	**Manufacturer**	**510k**	**Date**
	Brivant Ltd	K102211	03rd Sept 2010

Principle of Operation	The Victory guidewire is operated manually by a manual process.

Comparison of Technological Characteristics	The technological characteristics are substantially equivalent to the predicate devices. These performance properties include: - Same length range provided - All devices are constructed with a stainless steel core which is reduced in diameter at the distal end to provide flexibility - The proposed models have equivalent tip stiffness characteristics to the predicate devices. - All devices have a hydrophilic coating at the distal tip - All devices have a PTFE coating on the guidewire shaft - All devices are sterilized using ETO gas
Performance Testing (non-clinical)	In vitro bench tests were carried out to demonstrate equivalence with reference to the FDAs guidance document "Coronary and Cerebrovascular Guidewire Guidance, Jan 1995". The following bench tests were performed: - Tensile Strength - Torque Strength - Outer Diameter & Length Measurement - Torque Response - Catheter Compatibility - Coating Adherence/Coating Integrity - Particulate Testing - Tip Flexibility The results from these performance evaluations demonstrated that the Victory range met the acceptance criteria defined in the product specification and performed comparably to the predicate device(s). Biological Safety of the device has been established through biological risk assessment, chemical characterisation and biocompatibility testing carried out in compliance with ISO 10993-1.
Conclusions	Based on safety and performance testing, technological characteristics and the indications for use for the device, the Victory Guidewire has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 14 2012

Brivant, LTD.
c/o Mr. Kenneth Walsh
Senior QA/RA Engineer
Parkmore West Business Park
Galway
Ireland

Re: K120137
Trade/Device Name: Victory Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: January 9, 2012
Received: January 17, 2012

Dear Mr. Walsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120137

Device Name: Victory Guidewire

Indications For Use: The guidewires are intended to facilitate the placement and exchange of balloon catheters or other interventional devices within the peripheral vasculature during Percutaneous Transluminal Angioplasty (PTA) or other intravascular interventional procedures.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120137